

PROFESSIONAL SUMMARY

Highly experienced Quality Control professional. Extensive data management expertise for Stability and Product Release testing. Outstanding retention, inventory management and data collection skills. Proficient in Excel and MS Word and Detail Oriented.

EXPERIENCE

U MASS MEDICAL SCHOOL – MASSBIOLOGICS, Boston, MA

1991 – 2011

Documentation Coordinator III, Product Release (additional responsibilities)

- Participated in biennial FDA inspections
- Compiled and organized data to prepare Lot Release Protocols for submission to FDA
- Maintained product release master files
- Managed trending data base of product release testing for Quality Assurance Annual Manufacturing Reports
- Performed cGMP compliance review of quality control data
- Compiled data for Regulatory Affairs and Quality Assurance
- Coordinated shipment of bulk vaccine samples to FDA (CBER)
- Managed retention sample inventories
- Coordinated sample and documentation to support all manufacturing operations
- Coordinated testing schedule and managed documentation of Annual Visual Inspection of Product Reserves

Documentation Coordinator III, Stability (Promoted)

- Drafted and approved stability protocols for FDA licensed vaccine and IND monoclonal antibody products
- Compiled, organized and distributed quarterly stability reports to senior management
- Prepared monthly progress reports for licensed vaccine and IND products
- Maintained stability calendars and ensured the stability studies were initiated in a timely manner and according to regulatory requirements
- Managed stability retention sample inventories
- Distributed samples to appropriate labs for testing

Laboratory Technician

- Visual Inspection of Final Vial Product
- Prepared Visual Inspection Reports of licensed vaccine and IND products
- Maintained Central Receiving documentation and coordinate sample delivery
- Managed retention sample inventories
- Performed Annual Visual Inspection of Product Reserves
- Performed quarterly calibrations of manufacturing incubators, refrigerators and freezers

FABTRON CORPORATION, Waltham, MA

1981 – 1990

Supervisor

Programmed numerically controlled punch press machines using customer drawings

- Supervised the set up and operation of numerically controlled punch press machines
- Shipping/Receiving supervisor
- Ordered raw materials
- Machine operator